

## CLAIMS

1. A monoclonal antibody suitable for monitoring the activity of systems involving protein C inhibitor, said  
5 monoclonal antibody having specific affinity for both

i) a complex between a serine proteinase and an inhibitor thereof, and

ii) a cleaved and uncomplexed form of said inhibitor,

10 while having substantially no specific affinity for said inhibitor in its uncleaved and uncomplexed form; or a derivative thereof having the same biological activity.

2. A monoclonal antibody according to claim 1,  
15 wherein said monoclonal antibody is obtainable by immunisation of an animal with a mixture of

i) a complex between a serine proteinase and an inhibitor thereof, and

20 ii) a cleaved and uncomplexed form of said inhibitor,

followed by screening for and isolation of said monoclonal antibody.

3. A monoclonal antibody according to claim 2,  
25 wherein said animal is a mouse, preferably a Balb/c mouse.

4. A monoclonal antibody according to any one of the preceding claims, wherein said serine proteinase is selected from the group consisting of activated protein C (APC), thrombin, coagulation factor X<sub>a</sub>, trypsin, chymo-  
30 trypsin, urokinase plasminogen activator (uPA), tissue type plasminogen activator (tPA), plasma kallikrein, factor XI<sub>a</sub>, HGK1 and prostatic specific antigen (PSA).

5. A monoclonal antibody according to any one of the preceding claims, wherein said inhibitor is protein C inhibitor (PCI) or  $\alpha_1$ -antitrypsin.  
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6. A method for preparation of a monoclonal antibody as defined in any one of claims 1-5, wherein an animal is immunised with a mixture of

- i) a complex between a serine proteinase and an inhibitor thereof, and  
ii) a cleaved form of said inhibitor,

followed by screening for and isolation of said monoclonal antibody.

7. A method for preparation of a monoclonal antibody according to claim 6, wherein said animal is a mouse, preferably a Balb/c mouse.

8. A method for monitoring the activity of systems involving protein C inhibitor, wherein a monoclonal antibody as defined in any one of claims 1-5 is used in an immunoassay.

9. A method according to claim 8, wherein said immunoassay comprises a sandwich-type immunoassay.

10. A method according to claim 9, wherein said sandwich-type immunoassay is a technique comprising a tracer agent and said monoclonal antibody bound to a surface.

11. A method according to claim 10, wherein said tracer agent comprises an antibody having specific affinity for said serine proteinase or an epitope shared by said serine proteinase and said inhibitor.

12. A method according to claim 11, wherein said tracer agent is conjugated to a suitable enzyme and/or labelled with a tracing substance.

13. A method according to claim 12, wherein said enzyme is an alkaline phosphatase, horse radish peroxidase or a  $\beta$ -galactosidase.

14. A method according to claim 13, wherein said tracing substance is  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $\text{Eu}^{3+}$  or  $\text{Sm}^{3+}$  or a similar lanthanide.

15. A method for diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders

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involving lupus anticoagulants, wherein a monoclonal antibody according to any one of claims 1-5 is utilised.

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5 16. A method for diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants, wherein a method according to any one of claims 8-14 is utilised.

10 17. Use of a monoclonal antibody according to any one of claims 1-5 for in vitro diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants.

15 18. Use of a method according to any one of claims 8-14 for in vitro diagnosis of venous thrombosis, arterial thrombosis, embolism, coronary infarction, disseminated intravascular coagulation or disorders involving lupus anticoagulants.

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20 19. A kit for qualitative or quantitative determination of the activity of systems involving protein C inhibitor comprising a monoclonal antibody according to any one of claims 1-5.

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